**Supplementary Table 1: Comparison of PARENT recommendations with nine relevant published guidance documents (this is a detailed version of Table 3)**

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **PARENT recommendations** | | **Comparison with PARENT criterion (number of corresponding criterion)** | | | | | | | | |
| **Dimension** | **Subdimension** | **NICE** | **Swiss standards** | **FDA** | **Eucomed** | **ReBIP** | **IMDRF** | **ACSQHC** | **AHRQ** | **EPIRARE** |
| **GOVERNANCE** | Procedures and methods for registry operation and governance |  | 2 | 1.9 | 2.1, 2.2, 4.1, 5 | 2.3, 4.1 | 4.1 | 7 | 1 | 1.3, 1.4, 1.5, 2.2 |
| Education and training |  |  |  | 6.1-6.4 |  |  |  | 1 |  |
| Resource planning and financial sustainability |  | 1.5, 2.1 |  | 3.1, 3.2, 3.3 | 1.3, 5.1 |  | 1.6, 2.1, 6.5, 8.1, 11 | 1 |  |
| Interoperability |  | 1.3, 4(b), 5.3 |  | 2.7 |  | 1, 2, 10, 11, 12, 14, 15, 16, 17, 19 | 2.4, 2.7 | 4 | 1.7 |
| Self-assessment |  | 6 | 3.1, 3.2, 3.5, 3.6, 3.7 | 1.2., 2.3, 4.2, 4.3, 4.4 | 2.2, 2.3 | 4, 15 | 3.3, 6 | 3.2, 6 | 1.8, 2.1, 2.3, 3.5 |
| Expert guidance | 1 | 3 |  |  | 1.2 | 4.2 | 3.3, 7.1 | 1,2 |  |
| **DATA QUALITY** | Accuracy | 2 | 6.1 | 1.4,1.5 |  | 2.3 | 8 | 6.2, 6.3, 6.4 | 3.2, 3.4 | 2.2, 3.4, 3.5 |
| Completeness | 1 |  | 3.3 | 1.6 | 2.2 | 6, 7 | 1.7, 6.3 | 3.2, 3.4 | 2.2, 3.5 |
| Interpretability and Accessibility |  |  | 1.7, 2.2, 2.3 |  |  | 1, 2, 10, 11, 12, 14, 15, 16, 17, 19 | 2.3 2.5, 8.2 | 3.2, 3.4 | 3.4 |
| Relevance | 2 | 5.1 | 1.1, 1.2, 1.3, 1.6 |  |  |  | 1.3 | 3.2, 3.4 |  |
| Timeliness |  |  | 2.4, 2.8 |  |  |  | 2.2 | 3.2, 3.4 | 2.3 |
| Coherence |  | 5.1 | 2.2, 3.4 |  |  | 9 | 2.4, 2.7 | 3.2, 3.4 | 1.5, 1.6, 2.2, 3.5 |
| Mode of data collection and impact on data quality |  | 5.3 | 2.1, 2.2, 2.3, 2.4, 2.5, 2.6, 2.9 | 1.7, 2.7, 5.1 |  | 2, 3.2, 13 | 1.2, 1.3, 1.4, 1.7, 2, 3, 4, 6 | 3.2 | 1.5 |
| **INFORMATION QUALITY** | - |  | 3.2, 5.5, 5.6, 5.7 |  |  | 4.1 | 18, 19 | 10 | 3.4 |  |
| **CONFIDENTIALITY, SECURITY, PRIVACY, ETHICAL ISSUES, SECONDARY USE OF INFORMATION** | - | 4 | 4,N/A - EU regulation not applicable in Switzerland | 2.10 |  | 2.1, 3.1 |  | 5, 8, 9 | 2 | 2.2, 2.3 |
|

**Supplementary Table 2: Recommendations for registries from the PARENT guidelines**

|  |  |  |  |
| --- | --- | --- | --- |
| **Dimension** | **Subdimension** | **Criterion** | **Indicator(s)** |
| **GOVERNANCE** | Procedures and methods for registry operation and governance | Clearly stated purpose, structures, protocol/ procedures and information governance policies | Registry manual |
| Formal plan for registry governance and oversight covering overall direction and operations, scientific content, ethics, safety, data access, publications, and change management. |
| Education and training | Registry staff as well as data providers should receive formal and refresher training on registry procedures | Training plan and record of training sessions |
| Resource planning and financial sustainability | Resources should be adequate to ensure the sustainability, continual relevance and maximum impact of the data for which the registry holders are responsible | Registry size and duration defined |
| Interoperability | Interoperability principles should be applied to all aspects of registry including establishment, development, operation, use and governance to support national and international collaboration | Use of semantic standards, models and tools |
| Procedures for granting access to or sharing data (nationally or internationally) in place, including response time targets |
| Self-assessment | Self-assessment should serve to identify sources of potential data quality issues and assess them by using indicators on data quality dimensions, developing measurements for evaluation, subsequently used to correct issues and track improvements (essentially data/quality improvement) | Formal audit and quality assurance plan |
| Establishment of a Quality Assurance Committee |
| Expert guidance | The establishment of an Advisory Board consisting of a knowledgeable panel with expertise relevant to the registry domain and committed to the registry | Establishment of Advisory Board |
|
| **DATA QUALITY** | Accuracy | How well information in or derived from the data reflects the reality it was designed to measure | Validity exercise against gold standard |
| Completeness | Extent to which all necessary data that could have registered have actually been registered (coverage) |  |
|
| Interpretability and Accessibility | This includes the ease with which the existence of information can be ascertained, the suitability of the form or medium through which the information can be accessed, whether data are accompanied with appropriate metadata and whether information on their quality is also available (including limitation in use, generalisability and representativeness of registry) | Metadata and data dictionary available |
| Membership of yellow-page type services like PARENT Joint Action Registry of Registries, AHRQ Registry of Patient Registries or other specialized “umbrella” registry |
| Relevance | The degree to which data meet the current and potential needs of users | Stakeholder analysis |
|
| Timeliness | How current or up to date the data are at the time of release | Average gap between end of reference period for data and date available to users |
| Coherence | Coherence covers the internal consistency of data collection as well as its comparability both over time and with other data sources | Use of standard data definitions and a common data element to enable linkage |
| Mode of data collection and impact on data quality | How well data collection is integrated into the working practice of data providers | Electronic data collection |
| Minimal dataset |
| Data collection template |
| **INFORMATION**  **QUALITY** | - | The extent to which registry data are being used for their original purpose | Recent publications from registry data |
| Data briefings/summary statistics available |
| Establishment of Scientific Committee to guide scientific utilisation of registry data and assess external applications for utilisation of data |
| Use of registry data in health service research/quality improvement/policies |
| **DATA PROTECTION** | - | The safeguards put in place to protect patient privacy and confidentiality | Information governance policy |
| Registry adheres to Data Protection Directive (95/46/EC) or upcoming European Data Protection Framework | Privacy impact assessment |

**Supplementary Table 3: NICE quality standards for registries recommended by the International Procedures (IP) Programme**

|  |  |
| --- | --- |
| **Number** | **Quality standard** |
| 1 | All known procedures (all devices), without exception, are recorded in the database |
| 2 | The data recorded address relevant efficacy and safety outcomes and important patient characteristics |
| 3 | There is independent oversight of the register |
| 4 | The register complies with the data protection principles laid out in the UK Data Protection Act 1998 and any other relevant legislation |

**Supplementary Table 4: Swiss recommendations for the development and operation of health-related registries**

|  |  |  |
| --- | --- | --- |
| **Number** | **Dimension** | **Criterion** |
| 1 | Preparatory work at the planning stage | 1.1 The need for the registry and the benefits are specified for all parties, including patients. |
| 1.2 The legal framework is clarified. |
| 1.3 Integration of the registry is defined. |
| 1.4 The context and any competing interests are transparently disclosed. |
| 1.5 Development and longer-term funding are assured, a financial plan is available. |
| 2 | Registry design | 2.1 The aims and functions are clearly defined, and the questions to be pursued are formulated. |
| 2.2 The organisation of the registry is clearly described in a plan / regulation. |
| 3 | Expertise required for registry management | 3.1 The managers’ expertise matches the aims of the registry. |
| 3.2 Scientific expertise is assured (methodology, clinical expertise in the relevant area). |
| 3.3 Technical expertise is available (registry development, processes, logistics, database quality and security.) |
| 4 | Data protection and data ownership | 4.1 Data regulations are available, covering the following points: |
| a) Protection of privacy: description of data anonymisation / coding processes and informed consent, as well as the right to inspect data, management of revocation of consent and data storage. |
| b) Data access / data ownership / inspection and access rights / further use of data by third parties. |
| 5 | Data collection and data use | 5.1 The data variables to be collected are clearly defined and adapted to the aims. |
| 5.2 Technical structures are adequate and capable of development. |
| 5.3 Linkage to administrative/official data or the option of integration into hospital information systems, (interoperability) is assured. |
| 5.4 A data flow diagram is available, clearly describing data collection, transmission and processing. |
| 5.5 An evaluation plan is available, precisely describing data analysis and the reporting of results. |
| 5.6 A publication plan is available, precisely describing the requirements, content and form of publication, as well as target groups. |
| 5.7 Further use of data for research is supported. |
| 6 | Quality assurance | 6.1 A validation plan is available, including periodic review procedures, to ensure data quality. |
| 6.2 The registry’s aims and functions are periodically evaluated for their appropriateness. |
| 7 | Change of purpose and dissolution | 7.1 Processes for a change of purpose are defined. |
| 7.2 Processes for dissolution of the registry are defined. |

**Supplementary Table 5: Recommendations from FDA for the use of Real-World Evidence to Support Regulatory Decision-Making for Medical Device**

|  |  |  |  |
| --- | --- | --- | --- |
| **Number** | **Dimension** | **Subdimension** | **Factors related to the dimension** |
| 1 | Relevance |  | * 1. Regulatory relevance of RWD and the data source means that the data adequately addresses the applicable regulatory question or requirement, in part or in whole.   2. The representativeness of the device use in a real-world population as captured within the data source and the generalizability of the data to the relevant population being evaluated;   3. The use and recognition of the RWD source regionally, nationally and/or internationally, and the overall percentage of patient care encounters with the device that are captured   4. Validation protocol and resultant data to evaluate how well the RWD source reflects the patient population’s experience;   5. Whether the RWD contains elements to capture specific device identification information (e.g., unique device identifier)   6. Whether the data elements available for analysis will be capable of addressing the specified question when valid and appropriate analytical methods are applied   7. Whether any linkages performed are scientifically appropriate and undertaken to account for differences in coding and reporting across sources   8. Data source reporting schedule, including time interval between database close and release, and length of reporting periods   9. The prior documented (e.g., peer reviewed publications or practice guidelines) use of the data source for determining outcomes-based quality assessments, validated predictive risk modeling, signal detection, performance improvement benchmarking, and other clinically-meaningful uses |
| 2 | Reliability | Data accrual | * 1. The preparedness of individual sites for complete and accurate collection of observational data (e.g., defined processes, site training and support, dedicated qualified personnel)   2. use of a common data capture form;   3. use of a common definitional framework (i.e., data dictionary);   4. adherence to a common temporal framework for collection of key data points;   5. the data collection procedures, data evaluation protocol or statistical analysis plan including when the data collection procedures were developed relative to actual data evaluation (i.e., prospective vs. retrospective);   6. the sources and technical methods used for data element capture (e.g., chart abstraction, point of care entry, EHR integration, UDI capture, data records from device, linkage to claims data);   7. patient selection and enrollment criteria that minimize bias and ensure a representative real-world population (e.g., all-comer’s design, consecutive patient enrollment)   8. the timeliness of data entry, transmission, and availability;   9. whether the act of collection of data impacts the ability to measure treatment outcomes;   and 2.10 whether necessary and adequate patient protections were in place (e.g., de-identified data, maintenance of privacy, and need for informed consent as determined by the reviewing IRB and in compliance with FDA regulations). |
| 3 | Reliability | Data assurance - Quality Control | * 1. assessments of data quality (e.g., abstracted from verifiable source);   2. adherence to source verification procedures and data collection and recording procedures for completeness and consistency;   3. completeness (i.e., minimized missing or out of range values);   4. data consistency across sites and over time;   5. evaluation of on-going training programs for data collection and use of data dictionaries at participating sites;   6. evaluation of site and data monitoring practices; and   7. the use of data quality audit programs. |

**Supplementary Table 6: Recommendations from Eucomed for the Medical Device Registries: Six Key Principles**

|  |  |  |
| --- | --- | --- |
| **Number** | **Dimension** | **Criterion** |
| 1 | Scope | 1.1 What is within the scope of the registry and what is not? |
| 1.2 Has a robust evidence assessment been completed to ensure that the data to be collected by the registry is needed and clinically meaningful? |
| 1.3 Are there better ways to go about the investigation and are there other activities in the field that are on-going already? |
| 1.4 What is the main research question (clinical or economic) and can it effectively be answered by the data collected in the registry (what registry can and cannot do, what are the endpoints)? |
| 1.5 Will answering the question have a significant impact on public health or patient care to warrant the investment in the registry? |
| 1.6 Is the data identified to be collected in the registry sufficient to address the questions - is there too much or not enough data being collected for the appropriate period of time to answer the question? |
| 1.7 Is there a minimum set of data to be collected that was agreed internationally in this field to potentially allow for cross-country comparisons? |
| 1.8 How will new and/or innovative medical devices be treated after the set-up of the registry? |
| 2 | Governance | 2.1 Commonly accepted, trusted and approved coordinator should be appointed. |
| 2.2 Data governance committee and written procedures for data ownership, data access, data analysis and data use before initiation of registry should be developed. |
| 2.3 Appropriate quality assurance plans including plans for periodic auditing of the registry should be set up. |
| 2.4 Broadly inclusive forums to engage with different stakeholders should be created. |
| 2.5 Potential synergies with other national or international registries should be explored. |
| 2.6 Successful on-going registry experience and efforts should be leveraged. |
| 2.7 Internationally agreed minimum data sets should be created to be able to share data across registries |
| 3 | Financing | 3.1 Address the funding challenges of a registry from the beginning. |
| 3.2 Make sure that funding is sufficient for the set-up and sustainable running of the registry. |
| 3.3 Make sure that all stakeholders interested in participating in the registry and in the data it produces are considered and consulted on funding or contributing to the registry. |
| 4 | Data quality and data protection | 4.1 Develop methodological guidance to provide the opportunity for obtaining reliable data to contribute to high-quality evidence. |
| 4.2 Conduct in-depth risk analysis to assess the registry’s ability to obtain the quality data necessary for a pre-defined robust analysis and frequent reporting. |
| 4.3 Leverage experience and expertise from other types of activities like e.g. clinical trial data collection. |
| 4.4 Develop an automated data quality assurance system to verify adherence to the data quality monitoring plan which was developed prior to enrolment. |
| 5 | Data availability and reporting | 5.1 Provide definitions, explanations and methodologies on how data has been collected |
| 5.2 Establish clear roles regarding access to data for different users (primary users, secondary users) |
| 5.3 Establish the form in which data will be made available to primary and secondary users, including level of detail, numerical presentation and statistical analyses |
| 5.4 Establish publication policy plan |
| 5.5 Publish an on-line annual report including a patient-specific summary |
| 5.6 Establish a process for data requests |
| 6 | Staff education and qualification | 6.1 Standardised training programs should be developed and made available to the staff involved in registries to ensure quality of data entered |
| 6.2 other stakeholders involved in analysing and assessing registry data to help them understand the limitations and benefits of registry data |
| 6.3 students as part of their curriculum to ensure proper qualification for possible future participation in registries |
| 6.4 Instruments to motivate entering complete data sets should be in place. |

**Supplementary Table 7: Guidance on the Safety and Efficacy of Interventional Procedures/Assessment of the Quality of an Existing Database**

**(ReBIP, Review Body for Interventional Procedures)**

|  |  |  |  |
| --- | --- | --- | --- |
| **Number** | **Main criteria** | **Subdimension** | **Explanation** |
| 1 | Management and organisation | Focus | 1.1 The database should have a clear aim. Poorly defined aims may lead to inappropriate collection of data (irrelevant or poor quality). |
| Team | 1.2 Effective leadership by a well organised multi-disciplinary team is considered a hallmark of a good database. Leadership refers to more than those tasked with data gathering or inputting, as it encompasses all those who are charged with the management of the database and the determination of its trajectory. The team may include interested clinicians, epidemiologists, health service researchers, statisticians and IT professionals in order that the database in its totality can be directed and managed. |
| Funding | 1.3 The database should have secure long-term funding to enable it to carry on its work for as long as is required. Funding itself may come from research or other grants or there may be support from a professional body. |
| 2 | Data set and quality | Security | 2.1 It is important that all relevant legislative requirements on data security and handling are complied with. This covers such matters as the storage of data (whether paper or electronic), its movement or transmission to and from the database and access to the stored data.  Procedures should be in place that clearly address these issues. There are serious legal and ethical implications for a database that fails to observe these precautions and failure to tackle these issues may indicate weaknesses or poor practice elsewhere in the management of the database. |
| Compliance | 2.2 If the database is failing to pick up cases which ought to be registered (it records a low proportion of the “relevant population”) this will degrade the quality of any analysis that is undertaken. The database management team should have procedures for checking how complete the database is, for example, through surveying of clinicians in specialist societies. |
| Validation | 2.3 Even if all suitable cases do make it onto the database there remains the question of the extent to which the recorded information reflects the actual clinical information on which it is supposedly based. There should be a plan for validating and checking input data to ensure that what is recorded is accurate. If validation either cannot or is not being undertaken then this will cast doubt on the value of analytical output. However, validation may be expensive and time-consuming so may be seen as a less practical option formdatabases with limited funding. |
| 3 | Ethics and governance |  | It is possible that the database will need to be approved by an ethics committee if the remit of its data gathering exceeds that information which is routinely collected for these individuals as part of their normal care. While this aspect of the database is not critical in a functional sense, there is an obligation on those who gather and handle data to ensure that they comply with all relevant UK (or European Union) requirements. |
| 4 | Data analysis |  | The managers of the database ought to have a plan of analysis and dissemination or may have already made available the results of previous analyses. Engagement with those who supply the data is important and provision of analysis at the local level can provide valuable feedback to individual reporting clinicians. |
| 5 | Commercial sponsorship |  | Records may be maintained by manufacturers of the use to which their products are put and the outcomes that result. The company may provide financial or other material backing to support such a database. That there is such a link to a commercial concern may not in itself compromise the value of the database, although there appears no discussion of this in the literature. It would seem more useful to assess this type of database in the same way that a professional society database would be assessed. |

**Supplementary Table 8: Principles of International System of Registries Linked to Other Data Sources and Tools**

**Key** **Recommendations of the IMDRF Registry Workgroup**

|  |  |  |
| --- | --- | --- |
| **Number** | **Component** | **Desirable Characteristics** |
| 1 | Use of controlled vocabularies (standardized data dictionaries) | 1.1 Predefined standard data elements, preferably characterized per the ISO/IEC 11179 metadata standard |
| 1.2 Inclusive of all classes of data in the registry (patient demographics, clinical characteristics, procedure details, operator information, device data, clinical outcomes, administrative information) |
| 1.3 Baseline clinical characteristics and definitions consistent across jurisdictions (e.g., published as a clinical data standard in the medical literature, or a published registry data dictionary) |
| 1.4 Specific attention to the use of consistent and standardized clinical outcome definitions across jurisdictions, both short-term and long-term |
| 1.5 Use of common data elements in medical device identification developed by the IMDRF RPS workgroup |
| 1.6 Demonstrated syntactic and semantic interoperability via standard data exchange mechanisms (e.g., source data available in an HL7 Fast Healthcare Interoperable Resource |
| 2 | Use of a common data model (e.g., Observational Medical Outcomes Partnership Common Data Model) | 2.1 Standardized organization, format and content of observational data, at a minimum organizing person, conditions, drug, device, procedure and visit information in discrete tables, rather than a transaction-oriented organization of the data |
| 2.2 Enables use of standardized applications, tools and methods to be applied to the data |
| 2.3 Explicit requirement of unique patient identification at the individual patient level, specifically managing the patient as a single entity throughout the registry and enabling deterministic matching across data streams external to the registry |
| 2.4 Facilitates the linking of long-term observational information to the individual patient |
| 3 | Inclusion of device-related performance and device outcomes information | 3.1 Registry specification to require prompting at the point of care for device-related information whenever a device is implanted, adjusted / altered, or explanted. This assumes the ability to track patient and device- related events across time and health delivery systems. |
| 3.2 Data collection embedded in clinical device structured reporting processes |
| 4 | Implementation of a data quality plan for the evaluation and assurance of the quality and provenance of the data | 4.1 Inclusive of components of monitoring, auditing, and validation. The patient must be tracked across time and healthcare systems. |
| 4.2 Consistent with the requirements of regulatory bodies to accept and processes registry data |
| 5 | Governance that anticipates the conduct of analyses across different types of analysis frameworks | 5.1 Parsimonious approach to identifying the volume and variety of data to be collected, to be based primarily on anticipated analyses 5.2 Registry capacity to function as the analysis center, wherein analyses are conducted of data managed primarily or solely within the registry  5.3 Registry positioned to participate in a distributed data environment, wherein analyses are conducted at an analysis center of source data that is linked (via patient and / or device identifiers) across different data sources 5.4 Registry positioned to participate in a distributed analysis environment, wherein an analysis center requests a derived analytic output to be aggregated with those of other data centers |

**Supplementary Table 9: Recommendations of the IMDRF Registry Workgroup related to data quality**

|  |  |  |  |
| --- | --- | --- | --- |
| **Number** | **Dimension** | **Subdimension** | **Description** |
| 6 | Data Quality | Coverage | Completeness of participation for targeted data collection (e.g. out of a targeted group of 100 hospitals providing care, how many participate and what percent of cases are recorded within registry). This can be measured by comparing registry data with a verified external data source, to assess the extent to which all records are recorded within the registry. |
| 7 | Completeness | The extent to which data items used within analyses are consistently captured within the registry. Mandatory fields will be populated in all cases (where electronic data capture is used). Optional fields or paper-based capture will reduce the proportion of cases for which a data item is recorded. For example, if capturing details of the device is not mandatory this will significantly reduce the extent to which a regulator is able to draw conclusions from the data. |
| 8 | Accuracy | The extent to which data recorded in the registry is an accurate reflection of the healthcare event – e.g., correct patient age, correct device, and correct procedure type. Assessment of the accuracy may be difficult to measure but as with case ascertainment is reliant upon validation against external data sources, or completion of external audit and review to compare registry data with local records. |
| 9 | Consistency | The uniformity to which registry cordinators follow the same processes and procedures for data capture, including harmonized data definitions and relative stability in Case Report Form versioning. |
| 10 | Integrity | For regulatory use, it is essential that medical devices are uniquely identified within the registry, and that the unique identifiers are consistently recorded – such that all procedures using a device can be identified and analyzed. |
| 11 | Reliability | The extent to which data elements are reproducible. For example, if the New York Heart Association Functional Class differs by informant for the same patient, the data element would be considered unreliable. |

**Supplementary Table 10: Recommendations of the IMDRF Registry Workgroup: Assuring Analysis Validity when Linking Data Sources**

|  |  |  |
| --- | --- | --- |
| **Number** | **Dimension** | **Explanation** |
| 12 | Controlled vocabularies | The use of standardized common data elements that accomplish syntactic and semantic interoperability of the data among computer systems is a requisite condition. This includes standardized data elements representing clinical, technical, procedural, and administrative concepts, along with the structured documents thereof to transport data from one system to another. |
| 13 | Structured and semi-structured data capture at the point of care | The multi-stakeholder dialogue should lead to development of processes that capture registry data. This includes specifying information that should be collected as data, integrating clinical workflows with the process of data acquisition, utilizing all members of the healthcare team in capturing data, transitioning from a paper-based paradigm of transaction-based reports to an informatics-based paradigm that enables “collect once, use many times”, and even recommending that a common data model be used as the architecture in the respective IT systems. |
| 14 | Registry informatics | Registries are uniquely positioned to serve as the data hub to provide a systematic perspective of device performance. One of the keys to registry activities is having a common data model for the information framework. Of specific note: the common data model explicitly requires unique identification of patients as single individuals wherever included in a registry, and also requires identification of devices on a detailed level, particularly with respect to longitudinal follow-up and outcomes assessment. |
| 15 | Data quality assurance and supplementation | “Cleaning” of the data, is an important step to addressing data quality limitations of data collected via routine clinical processes, particularly when that data will be analyzed for evaluating quality assessment, process improvement, and outcomes determinations. |
| 16 | Data packaging and upload of data to registries | The submission of “clean”, packaged data per registry schemas often requires some degree of conversion from clinical representations in health records and ancillary systems to formats consistent with the technical requirements of the recipient registries. |
| 17 | Unique device identification | The device identifier of the UDI is a great example of a unique key that could be used to link data. Until the device identifier of the UDI is more completely integrated into device registries, it will be necessary to identify several keys that could be used to pull and link data. |

**Supplementary Table 11: Operating Principles and Technical Standards for Australian Clinical Quality Registries (ACSQHC)**

|  |  |  |
| --- | --- | --- |
| **Number** | **Dimension** | **Operating Principle** |
| 1 | Attributes | 1.1 Australian Clinical Quality Registries should be developed with clear and precisely defined purposes. |
| 1.2 For Australian Clinical Quality Registries to provide the maximum value to the health system they should focus their core data collection on the essential elements required to serve their main purposes. |
| 1.3 Data collected by Australian Clinical Quality Registries should be confined to items which are epidemiologically sound, i.e. simple, objective, and reproducible; |
| 1.4 Methods used to collect data in Australian Clinical Quality Registries should be systematic, with identical approaches used at the different institutions contributing information. |
| 1.5 Outcome determination should be undertaken at a time when the clinical condition has stabilised and the outcome can therefore be reasonably ascertained. |
| 1.6 In determining the time to outcome assessment, Australian Clinical Quality Registries must consider the burden and cost of data collection together with the likelihood of loss to follow-up. |
| 1.7 Australian Clinical Quality Registries must ensure that complete registry data are collected from the eligible population. |
| 2 | Data collection | 2.1 The collection of data for an Australian Clinical Quality Registry must not impact on the provision of health care and should not be a burden or incur a cost to consumers. |
| 2.2 Data capture should be performed as close as possible to the time and place of care by appropriately trained data collectors; |
| 2.3 Data should be uniformly and easily accessible from the primary data source. |
| 2.4 Standard definitions, terminology and specifications should be used in Australian Clinical Quality Registries wherever possible to enable meaningful comparisons to be made and to allow maximum benefit to be gained from linkage to other registers and other databases (if approved by relevant ethics committees, etc.). |
| 2.5 Australian Clinical Quality Registries must use data dictionaries when they are established to ensure that a systematic and identical approach is taken to data collection and data entry. They need to publish eligibility criteria, metadata, data dictionaries, etc.; |
| 2.6 To avoid duplicating data capture, Australian Clinical Quality Registries use data from existing data sources, including administrative data, where they are of a satisfactory quality; |
| 2.7 Australian Clinical Quality Registries should have the capacity to enhance their value through linkage to other disease and procedure registers or other databases. |
| 3 | Data elements | 3.1 Australian Clinical Quality Registries should collect individually identifiable patient or subject information. |
| 3.2 Where patterns or processes of care have an established link to outcomes and process measures are simple, reliable and reproducible, they should be considered for collection by Australian Clinical Quality Registries. |
| 3.3 Where possible, outcomes should be assessed using objective measures. Where this is not possible, outcome should be assessed by an independent person and undertaken using standardised and validated tools. |
| 4 | Risk adjustment | Australian Clinical Quality Registries should collect objective, reliable co-variates for risk adjustment to enable factors outside the control of clinicians to be taken into account by using appropriate statistical adjustments. |
| 5 | Data security | 5.1 To protect register data, Australian Clinical Quality Registries must utilise secure access controls and secure electronic transfer and electronic messaging systems. |
| 5.2 The collection, storage and transmission of clinical registry data must be in line with relevant legislation and guidelines. |
| 5.3 Institutional policy principles set out in Part B: Technical standards should be met. |
| 6 | Ensuring data quality | 6.1 Australian Clinical Quality Registries should report as a quality measure the percentage of eligible patients recruited to the registry. |
| 6.2 Australian Clinical Quality Registries should have a robust quality control plan which allows ongoing monitoring of the completeness and accuracy of the data collected. |
| 6.3 Australian Clinical Quality Registry data should be checked in a sample of cases. This usually involves audit against source records. The sample size needs to be sufficient to produce reliable measures of data completeness and accuracy. The frequency of audits needs to be sufficient for data quality lapses to be identified promptly. Incomplete or inaccurate data should be identified by the data centre and remedied as soon as possible. |
| 6.4 Australian Clinical Quality Registries should incorporate in-built data management processes such as data range and validity checks. |
| 6.5 Australian Clinical Quality Registry reports should be produced according to a strict timeline and should be appropriately funded to enable this to occur. |
| 7 | Organisation and governance | 7.1 Australian Clinical Quality Registries must formalise governance structures to ensure accountability, oversee resource application, provide focus and optimise output from the registry. |
| 7.2 Australian Clinical Quality Registries must establish policies to manage a range of contingencies arising from the analysis of data from the registry, which includes a formal plan ratified by the Steering Committee to address outliers or unexplained variance, to ensure that quality of care issues are effectively addressed and escalated appropriately. |
| 8 | Data custodianship | 8.1 Custodianship of clinical register data needs to be made explicit in Contracts and/or Funding Agreements. |
| 8.2 Data access and reporting policies for Australian Clinical Quality Registries should be made available to persons wishing to use register data. |
| 8.3 Third parties wishing to access data and publish findings must seek approval from the Steering Committee and obtain relevant Institutional Ethics Committee endorsement where identified or re-identifiable data or contact with patients is sought. |
| 9 | Ethics and privacy | 9.1 Institutional Ethics Committee (IEC) approval must be obtained to establish the Australian Clinical Quality Registry |
| 9.2 Registry personnel should be familiar with and abide by the requirements set out in relevant privacy legislation, the National Statement on Ethical Conduct in Human Research and the Australian Code for the Responsible Conduct of Research. |
| 9.3 Participants or their next of kin should be made aware of the collection of register data. They should be provided with information about the Australian Clinical Quality Registry, the purpose to which their data will be put and provided with the option to not participate. This should be at no cost to the registry participant. |
| 9.4 Where projects are undertaken using register data, IEC approval must be sought unless the project falls within the scope of an institution’s quality assurance activity. |
| 10 | Information output | 10.1 Data from Australian Clinical Quality Registries should be used to evaluate quality of care by identifying gaps in best practice and benchmarking performance. |
| 10.2 Australian Clinical Quality Registries must report without delay on risk-adjusted outcome analyses to institutions and clinicians. |
| 10.3 Local clinical register database managers should have the capacity to undertake ad hoc analyses of their data to enable monitoring of clinical care. |
| 10.4 Australian Clinical Quality Registries must produce a publicly-accessible aggregated annual report detailing clinical and corporate findings. |
| 10.5 Australian Clinical Quality Registries must have documented procedures for reporting on quality of care, including addressing outliers or unexplained variance. |
| 11 | Resources and funds | Australian Clinical Quality Registries should be appropriately funded to allow data collection, reporting and the institution of strong quality control procedures. |

**Supplementary Table 12: List of chapters from Registries for Evaluating Patient Outcomes: A User’s Guide (3rd Edition, Volume 1 & 2) (AHRQ)**

|  |  |  |
| --- | --- | --- |
| **Number** | **Dimension** | **Chapter** |
| 1 | Creating Registries | 1.1 Patient Registries |
| 1.2 Planning a Registry |
| 1.3 Registry Design |
| 1.4 Data Elements for Registries |
| 1.5 Use of Patient-Reported Outcomes in Registries |
| 1.6 Data Sources for Registries |
| 2 | Legal and Ethical Considerations for Registries | 2.1 Principles of Registry Ethics, Data Ownership, and Privacy |
| 2.2 Informed Consent for Registries |
| 2.3 Protecting Data: Confidentiality and Legal Concerns of Providers, Manufacturers, and Health Plans |
| 3 | Operating Registries | 3.1 Recruiting and Retaining Participants in the Registry |
| 3.2 Data Collection and Quality Assurance |
| 3.3 Adverse Event Detection, Processing, and Reporting |
| 3.4 Analysis, Interpretation, and Reporting of Registry Data To Evaluate Outcomes |
| 3.5 Modifying and Stopping Registries |
| 4 | Technical, Legal, and Analytic Considerations for Combining Registry Data With Other Data Sources | 4.1 Interfacing Registries With Electronic Health Records |
| 4.2 Linking Registry Data With Other Data Sources To Support New Studies |
| 4.3 Managing Patient Identity Across Data Sources |
| 4.4 Analysis of Linked Registry Data Sets |
| 5 | Special Applications in Patient Registries | 5.1 Use of Registries in Product Safety Assessment |
| 5.2 Rare Disease Registries |
| 5.1 Use of Registries in Product Safety Assessment |
| 5.4 Quality Improvement Registries |
| 5.5 Registries for Medical Devices |
| 6 | Evaluating Registries | Assessing Quality |

**Supplementary Table 13: Guidelines for data sources and quality for RD Registries in Europe (EPIRARE - European platform for Rare Disease Registries)**

|  |  |  |
| --- | --- | --- |
| **Number** | **Dimension** | **Subdimension** |
| 1 | Design and implementation | 1.1 As registries are in the framework of the epidemiological observational study designs, their development should bear in mind all steps which apply to these types of studies, from their original definition of aims and scopes to the presentation of the final results achieved |
| 1.2 The starting point has to be a good definition of aims and scopes and thereafter the bases for the rest of methods to be applied have to be set up, including quality related topics |
| 1.3 A detailed and comprehensive list of actions has to be defined, and associated procedures should be clearly described from the beginning of the process of the RD registry construction |
| 1.4 A Manual of Procedures containing all actions, procedures, and registries associated to the procedures (i.e.: incidental questions, backup dates, partners list and their capacities, etc) are two fundamental documents of the quality assurance plan |
| 1.5 The Manual of Procedures should also contain a list of Common Data Elements including their characteristics. From them, a minimum data set from the whole CDE should be stated as mandatory. They will be the fundamental elements for exploring the outcomes validity. |
| 1.6 A case standardized form should be provided to the partners and data have to be curated before being included in the database |
| 1.7 Standardized Operating Processes have to be developed for each one of the procedures included in the registry |
| 1.8 The use of some of the current quality guidelines for publishing results (i.e.: STROBE; STRENGTH; PRISMA, etc) is highly recommendable to communicate registries results |
| 2 | Quality control | 2.1 A quality assurance plan has to be designed, which should include quality criteria, quality indicators, quality control mechanisms, quality assessment processes and quality results |
| 2.2 The list of quality of indicators would contain topics related with the process, the monitoring and outcomes of the registry (i.e.:Surveillance of RD registry activities, Case ascertainment, Analysis of data completeness, Consistency, Timelines, Data security and confidentiality and Validity) |
| 2.3 Some assessment phases have to be included during the life of the registry at different periods. At each of these phases, a revision should be made of the development of a quality assurance plan and the quality control measures, indicators, data security and confidentiality, timeliness, reporting, coordination.The assessment phases should also include some external assessment |
| 3 | Cases and data | 3.1 Inclusion and exclusion case criteria as well as target population should be defined |
| 3.2 Analysis of sources of information and their capacity of providing valid information should be explored |
| 3.3 Case selection and case ascertainment are the two most important questions to minimize the selection bias |
| 3.4 Control of duplicates and minimizing the mistakes in the interpretation and diagnosis are important clues for the quality |
| 3.5 Errors in coding, data entry, data transformation, data consistency across sites and over time and Intentional errors should be care using electronic forms, personal acting as a data curators, external audits, among some other mechanisms |
| 3.6 Reliability and data accuracy have to be frequently explored |
| 3.7 Data completeness must be checked |

**Figure 1 Distribution of responses**

